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| APPLICATION NO | HIJNG DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKLENO. | CONFIRMATION NO |
|-----------------------------------|---------------|----------------------|-------------------------|-----------------|
| 09 904,200 | 07 11 2001 | Christopher S. Chen | 56252 | 1223 |
| | 90 04 14 2003 | | | |
| EDWARDS & ANGELL, LLP | | | EXAMINER | |
| P.O. BOX 9169 BOSTON, MA 02209 | | | NAFF, DAVID M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | 16 |
| | | | DATE MAILED: 04-14-2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

-The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address-Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication . - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Status Responsive to communication(s) filed on $\frac{17/24/62}{}$ ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 1 1; 453 O.G. 213. Disposition of Claims _____is/are pending in the application. Claim(s) _ is/are withdrawn from consideration. Of the above claim(s).... □ Claim(s) ___ is/are allowed. is/are rejected. Claim(s)___ _____is/are objected to. ☐ Claim(s)_ _ are subject to restriction or election Claim(s) requirement. **Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. ☐ The proposed drawing correction, filed on ______ is ☐ approved ☐ disapproved. ☐ The drawing(s) filed on ______ is/are objected to by the Examiner. The specification is objected to by the Examiner. ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 (a)-(d) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d). □ All □ Some* □ None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)). *Certified copies not received:_ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9, 11+13 Interview Summary, PTO-413 Attachment(s)

Office Action Summary

U. S. Patent and Trademark Office PTO-326 (Rev. 9-97)

Notice of Reference(s) Cited, PTO-892

Notice of Draftsperson's Patent Drawing Review, PTO-948

Part of Paper No.

☐ Notice of Informal Patent Application, PTO-152

Other

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In a response of 12/24/02 to a restriction requirement of 9/3/02, applicants elected Group V, canceled all claims in the application, and added new claims 64-90 that correspond to the invention of Group V.

Claims examined on the merits are 64-90 which are all claims in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 75-90 are rejected under 35 U.S.C. 112, first paragraph, as

15 containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support for the conditions of the claims is not readily apparent in the specification. While the amendment cites sections of the specification as providing support for the added claims, the specific claims have not been related to the specific sections in which support is found, and support for the above claims is not readily apparent in the sections cited. Applicants should point out the specific page and lines where conditions of each of the above claims are recited or supported.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is unclear in line 3 by reciting "on the substrate by cytophobic regions". It is suggested that "by" be changed to -- and --, and "on the substrate" by deleted.

Claim 65 is confusing by requiring the surfactant compound to not be covalently linked to the substrate since claim 64 requires the cytophobic regions to contain the surfactant. In line 2 of the claim, "substrate" should be changed to -- cytophobic regions --.

Claims 69 is unclear as to the meaning and scope of "the surface of the device comprises a polymeric material". Does this mean that a polymeric material is coated on the device or that the device is formed from polymeric material?

In claim 78, the meaning and scope of "block" is uncertain. Structures that are a block and not a block would be relative and subjective.

Claims 79-81 are unclear as to the relationship of the structure required to the substrate and cytophilic and cytophobic regions required in claim 64.

Claim 82 is unclear as to the relationship of the cytophilic and cytophobic regions required to the cytophilic and cytophobic regions required by claim 64. Are the regions of claim 82 in addition to those of claim 64?

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Claim 85 is unclear as to the meaning of "interconnected so as to form a network of cells". Structure having the cytophilic regions interconnected so the cells form a net work is unclear. Furthermore, the meaning and scope of "network of cells" is uncertain. It would be uncertain as to when cells are a network and not a network.

Claim 89 is unclear as to the part of the device that contains the polydimethylsiloxane. Does this material form the device or does it have some other function?

Claim 90 is confusing and unclear as to how the structures required 10 further modify the structure of claim 64. Also, how do these structures function in relation to the structure of claim 64?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

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examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (q) prior art under 35 U.S.C. 103(a).

Claims 64-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singhvi et al (6,368,838 B1) in view of Dewez et al (WO 96/15223).

The claims are drawn to a device containing a substrate having thereon a plurality of cytophilic regions that can adhere biomolecules and cytophobic regions to which the biomolecules do not adhere, and the cytophobic regions contain a surfactant compound.

10 Singhvi et al disclose a device having cytophilic islands for adhering cells and cytophobic regions which isolate the cytophilic islands. The cytophilic islands may contain extracellular matrix proteins (col 9, lines 32-33) to promote binding of cells (col 9, lines 22-26).

Dewez et al disclose a biomaterial for selective adhesion of cells or tissue which contains a polymeric support having a heterogeneous surface conditioned with a surfactant and an extracellular matrix protein. The extracellular matrix protein adheres to one surface area of the support and the surfactant adheres to another surface area where it 20 inhibits adsorption of the extracellular matrix protein (paragraph bridging pages 3 and 4). Cells preferentially adhere to the portion of the support containing the extracellular matrix protein (page 4, lines 12-16).

It would have been obvious to provide the cytophilic islands of the 25 device of Singhvi et al with extracellular matrix protein to enhance the

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binding of cells as suggested by Singhvi et al and Dewez et al, and it would have been obvious to provide the cytophobic regions of Singhvi et al with a surfactant to inhibit binding of extracellular matrix protein to these regions as suggested by Dewez et al. The conditions of dependent claims would have been matters of obvious choice within the skill of the art in view of the disclosures of the references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the
15 examiner's supervisor, Mike Wityshyn, can be reached at telephone number
(703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this 20 application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DMN

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